II. REMARKS

Formal Matters

Claims 1-22 are pending after entry of the amendments set forth herein.

Claims 8-12 and 21 were examined and were rejected. Claims 1-7 and 13-20 are withdrawn from consideration.

Claim 8 is amended. The amendment to claim 8 was made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendment to claim 8 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: paragraph 0068, 0077, and 0079; and paragraph 0029. Accordingly, no new matter is added by these amendments.

New claim 22 is added. Support for new claim 22 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: paragraph 0075. Accordingly, no new matter is added by this new claim.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Rejection under 35 U.S.C.§102

Claims 8-11 were rejected under 35 U.S.C.§102(a) as allegedly anticipated by Dynan (WO 99/33971; "Dynan").

The Office Action stated that Dynan teaches a method for identifying an agent that modulates a biological activity of DNA-PK, comprising adding an agent to be tested to a sample, the sample comprising DNA-PK and an immunomodulatory nucleic acid molecule; and detecting a biological activity of DNA-PK. Applicants respectfully traverse the rejection.

Dynan discusses oligomers that bind Ku protein. Dynan states that the oligomers that bind Ku protein are RNA oligomers. Dynan, page 7, line 9 to page 8, line 12; Table 1; and Example 4, page 45, line 1 to page 46, line 22.

Dynan neither discloses nor suggests that the RNA oligomers discussed therein are immunomodulatory nucleic acid molecules. Accordingly, Dynan cannot anticipate the instant invention as claimed.

Furthermore, Dynan states that the RNA oligomers discussed therein bind to Ku antigen and block the ability of Ku to activate DNA-PK. Dynan, page 45, lines 29-30; and page 46, lines 24-31. In contrast, as discussed in the instant specification, an immunomodulatory nucleic acid binds to Ku antigen, resulting in activation of DNA-PKcs. Specification, paragraph 0029. Accordingly, Dynan cannot anticipate the instant invention as claimed.

The Office Action stated that the rejection is based on the fact that nucleic acid molecules, capable of binding with Ku protein, can modulate the immune system, because Ku protein was first identified as an autoantigen in sera from certain patients with autoimmune disease, and Ku protein is the regulatory component of the DNA-dependent protein kinase. However, the presence of Ku antigen in sera of certain patients with autoimmune disease does not in any way lead to a conclusion that nucleic acid molecules capable of binding to Ku antigen modulate the immune system. The Office Action has provided no basis in fact for making such a conclusion.

Notwithstanding the above remarks, and solely in the interest of expediting prosecution, claim 8 is amended to recite "wherein the immunomodulatory nucleic acid molecule is a DNA molecule that, when bound to Ku antigen, activates DNA-PKcs." Dynan neither discloses nor suggests a method as claimed, comprising adding an agent to be tested to a sample, the sample comprising DNA-PK and an immunomodulatory nucleic acid molecule, under conditions which favor binding of the immunomodulatory nucleic acid molecule to DNA-PK, thereby forming a test sample, wherein the immunomodulatory nucleic acid molecule is a DNA molecule that, when bound to Ku antigen, activates DNA-PKcs. Accordingly, Dynan cannot anticipate the instant invention as claimed.

Applicants submit that the rejection of claims 8-11 under 35 U.S.C. §102(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C.§103

Claims 12 and 21 were rejected under 35 U.S.C.§103 as allegedly obvious over Dynan in view of WO 99/11275 ("Raz").

The Office Action stated: 1) Dynan teaches the method of claims 8-11; 2) Dynan does not teach

a method wherein an amount of IL-12 produced by the cell is measured; 3) Raz teaches a method wherein the amount of IL-12 produced by the cell is measured; 4) Dynan does not teach a method wherein the immunomodulatory nucleic acid comprises a nucleotide sequence selected from 5'-purine-purine-C-G-pyrimidine-pyrimidine-3'; and 5) Raz teaches a method wherein the immunomodulatory nucleic acid comprises a nucleotide sequence selected from 5'-purine-purine-C-G-pyrimidine-pyrimidine-3'. The Office Action concluded that it would have been obvious to combine and substitute the method wherein IL-12 is measured and the immunomodulatory nucleic acid comprises a nucleotide sequence selected from 5'-purine-purine-C-G-pyrimidine-pyrimidine-3' of Raz in the method of Dynan. Applicants respectfully traverse the rejection.

As discussed above, Dynan neither discloses nor suggests the instant invention as claimed. Raz does not cure the deficiency of Dynan.

Raz discusses modulating an immune response with an immunomodulatory nucleic acid. There is no disclosure whatsoever in Raz of a method of identifying an agent that modulates DNA-PK activity. There is no disclosure whatsoever in Raz that an immunomodulatory nucleic acid binds DNA-PK. The methods of Raz could not be "combined" or "substituted" with the methods of Dynan to arrive at the instant invention as claimed. Accordingly, Dynan, alone or in combination with Raz, cannot render the instant invention as claimed obvious.

Applicants submit that the rejection of claims 12 and 21 under 35 U.S.C. §103 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCAL168.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: May 21, 2003

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